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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,061	DUFF ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *2,4,6-16 and 18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/345,217.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/15/0 and 3/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and the –511 IL-1B marker in the reply filed on October 16, 2006 is acknowledged. The traversal is on the ground(s) that allele 4 of the 222/223 marker of IL-1A and allele 4 of the gz5/gz6 marker of IL-1A are often found together and a search for these inventions is co-extensive in that it involves a search of only IL-1A. This is not found persuasive because the elected invention of the –511 marker of IL-1B is distinct from IL-1A and thereby a search for IL-1A would not lead one to all references disclosing the –511 marker of IL-1B. Further, a search for allele 4 of the 222/223 marker of IL-1A and allele 4 of the gz5/gz6 marker are not in fact coextensive with one another. A complete search for allele 4 of the 222/223 marker of IL-1A would not lead one to all references for allele 4 of the gz5/gz6 marker, and vice versa. Additionally, the claims broadly recite kits comprising a means for detecting one of the stated alleles, wherein the means may be a primer (see, e.g., claim 3). Thereby, the claims encompass kits comprising primers such as SEQ ID NO :8 and 9 for the detection of the 22/223 marker and SEQ ID NO: 10 and 11 for the detection of the gz5/gz6 marker. However, one cannot identify references teaching SEQ ID NO: 8 and 9 for detection of the 222/223 marker by merely performing a literature search for the term "IL-1A." Nor can one identify all references teaching SEQ ID NO: 10 and 11 for the detection of the gz5/gz6 marker by performing a literature search for the term "IL-1A." A search for these sequences, and thereby a search for references teaching a means for detecting the 222/223 marker and the gz5/gz6 marker requires a search of the

sequences in the sequence databases. Yet, a search for SEQ ID NO: 8 would not lead one to all references teaching SEQ ID NO: 10 or 11, nor would a search for SEQ ID NO :10 or 11 lead one to all references teaching SEQ ID NO: 8.

The response further argues that the markers make up at most four nucleic acid sequences. This argument is not persuasive because, in fact, the claims encompass at minimum 19 distinct alleles and thereby 19 distinct nucleic acid sequences. Further, since the claims encompass primers and primer pairs for primer extension reactions, in addition to allele specific primers and probes, as the "means" to detect said allele, the claims encompass a significantly larger genus of nucleic acids.

The response argues that the markers make up a combination that, according to the MPEP cannot be restricted. However, claims 1,3, 5 and 7 do not in fact require a combination of markers, but rather allow for only one marker. Further, the restriction requirement did not preclude applicant from electing a particular combination of markers. The option to select a particular combination of markers is clearly set forth in the restriction requirement (see groups 19-153 as set forth on page 3 of the Office action of June 14, 2006).

The response also argues that the Director has partially waived the requirements of 37 CRF 1.141 and permits a reasonable number of sequences, normally ten sequences, to be examined in a single application. This argument has been fully considered but is not persuasive. With respect to claims to nucleic acids, the MPEP states that the requirements of 37 CFR 1.141 have been partially waived to "permit a reasonable number of such nucleotide sequences to be claimed in a single application."

The MPEP further states that "**normally** ten sequences constitute a reasonable number for examination purposes and that "**up to 10** independent and distinct nucleotide sequences" (emphasis added) may be examined in a single application. Thereby, the MPEP does not in fact state that 10 nucleotide sequences will be examined in each application. Rather, the MPEP 803.04 states that due to the complex nature of the claimed material, the reasonable number of sequences to be examined may be less than ten. In the present situation, searching ten or more distinct alleles and the multitude of different means for detecting the alleles (i.e., amplification primers, allele specific primers, allele specific probes, etc) constitutes a significant number of nucleic acids to examine due to the complex nature of the claimed material. The demand on the PTO's computers dedicated to sequence searches alone would be undue as would the time the examiner would need to review the finding of all the searches, in addition to literature searches that would be required. Furthermore, the claimed nucleic acids comprising distinct alleles consist of different nucleotide sequences, have different specificities of hybridization and different biological activities and effects. Accordingly, the nucleic acids have different structures and function and therefore it is proper to restrict the patentably distinct and independent inventions under 35 USC 121.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1, 3, 5 and 17 have been examined herein to the extent that the claims read on kits for the detection of the –511 marker of IL-1B. The non-elected subject matter of additional alleles set forth in claims 1, 3, 5 and 17, as well as claims 2,

4, 6-16 and 18-22, are withdrawn from consideration as being directed to a non-elected invention.

Specification

2. The disclosure is objected to because of the following informalities:

A. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, pages 23 and 32 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

B. Page 32, lines 5-7 of the specification refers to DNA sequences "shown in" Figures 1, 2 and 3. However, Figures 1 and 2 do not represent DNA sequences. It appears that the specification should refer to the sequences of SEQ ID NO: 1, 2 and 3, or to Figures 3, 4 and 5, rather than to Figures 1, 2 and 3.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 or 119 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

In the present application, the specification states that application 09/345,217 "claims the benefit of Foreign Application No. PCT/GB98/01481, filed May 21, 1998 and Foreign Application No. GB9711040.7." However, this statement does not clearly set forth the relationship between the "foreign applications" and the '217 application. In fact, Application 09/345,217 is the National Stage of PCT/GB98/01481. Thereby, the first line of the specification should be amended to recite, for example, that application '217 is the National Stage of International Application PCT/GB98/01481, filed May 21, 1998, which claims the benefit of Foreign Application No. GB9711040.7, filed May 29, 1997. Also, it is noted that the Oath/Declaration lists the PCT/GB98/01481 application as a prior foreign application, whereas, as indicated above, this application is the International Application.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite over the recitation of "said detecting means is selected from the group consisting of: a) allele specific oligonucleotide hybridization; b) size analysis...". The recite lists consists of methods rather than means for detecting an allele. Thereby, it is unclear as to how the kits can contain a method and it is unclear as to what constitutes the means for detecting one or more alleles. Also, in claim 3, the

phrase "said detecting means" lacks proper antecedent basis. The claim should be amended to refer to a "said means for detecting."

Claim 17 is indefinite over the recitation of "the nucleotide corresponding to allele 2 of the –511 marker of IL-1B" because this phrase lacks proper antecedent basis because the claim does not previously refer to a nucleotide of this allele. Further, the claim is indefinite over the recitation of "corresponding" because "corresponding" is not an art recognized term to describe the relationship between a nucleotide and a nucleic acid allele. It is not clear as to whether a corresponding nucleotide refers to nucleotide which is at the same position as, for example, position –511 or at any position in allele 2 or 1 of the –511 marker of IL-1B. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid sequences, one of skill in the art cannot determine the meets and bounds of the claimed subject matter. It is also unclear as to what is considered to be "the nucleotide" because allele 1 and 2 of IL-1B –511 includes all of the nucleotides of the IL-1B gene. Thereby, it is unclear as to whether this phrase is intended to refer to any nucleotide within the IL-1B gene or to a nucleotide at position –511 (i.e., a C or a T). In the later case it is unclear as to whether the claim encompasses any nucleic acid that hybridizes to any target comprising a C or a T or if the claim is intended to refer to only nucleic acids that hybridize to an IL-1B nucleic acid having a C or T at nucleotide position –511.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,713,253. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '253 are drawn to methods which require the use of the reagents of a means for detecting an allele 2 of the –511 marker of IL-1B, wherein the means is a restriction enzyme or a primer which hybridizes to IL-1B sequences, and thereby is a nucleic acids which hybridizes to allele 1 or allele 2 of the –511 marker of IL-1B. Regarding present claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the nucleic acids of '253 meet the limitations of the nucleic acids of present claim 17. The claims of '253 do not specifically recite packaging the detection means into a kit. However, reagent kits for

performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting allele 1 or allele 2 of the –511 marker of IL-1B of '253 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

6. Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,733,967. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '967 are drawn to methods which require the use of the reagents for detecting IL-1B (-511) allele 2, and particularly require the use of an allele specific oligonucleotide or the use of a primer for a primer specific extension. Regarding present claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the nucleic acids of '967 meet the limitations of the nucleic acids of present claim 17. The claims of '967 do not specifically recite packaging the detection means into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at

the time the invention was made to have packaged the means for detecting allele 2 of the –511 marker of IL-1B of '967 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B –511 allele 2.

7. Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,140,047. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '047 are drawn to kits which include a control nucleic acid comprising IL-1B –511 allele 2 – i.e., a nucleic acid which hybridizes to an IL-1B –511 allele 2. Accordingly, the kits of present claims 1, 3, 5 and 17 are obvious in view of the kits of '047 since it is a property of the nucleic acids present in the kit of '047 that they serve as a means to detect and to hybridize to nucleic acids comprising the IL-1B –511 allele 2 marker. Further, the claims of '047 include methods which require the use of amplification reagents and primers (i.e., SEQ ID NO: 3 and 4) which hybridize to IL-1B –511 allele 2 nucleic acids and can be used as a means for detecting IL-1B –511 allele 2 nucleic acids. Claims 3-15 of '047 do not specifically recite packaging the means for detecting IL-1B –511 allele 2 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 2 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

8. Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,686,246 (cited in the IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '246 are inclusive of kits and nucleic acid detection methods which require the use of primers for detecting the IL-1B -511 alleles (see SEQ ID NO: 1 and 2 therein; i.e., nucleic acids which hybridize to an IL-1B –511 allele and nucleic acids for primer specific extension), and also encompass means for detecting the IL-1B –511 alleles wherein the means is a restriction enzyme. Regarding present claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the nucleic acids of '246 meet the limitations of the nucleic acids of present claim 17. Claims 1-8 of '246 do not specifically recite packaging the means for detecting IL-1B –511 allele 2 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 2 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

9. Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,210,877. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a

means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '877 are drawn to methods which require the use of the reagents for detecting an IL-1B –511 allele 2, wherein the means is a restriction enzyme or a primer (see SEQ ID NO: 3 and 4 therein; which are considered to constitute a nucleic acid that hybridizes to an IL-1B – 511 allele, and a nucleic acid for primer specific extension). Regarding present claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the nucleic acids of '877 meet the limitations of the nucleic acids of present claim 17. The claims of '877 do not specifically recite packaging the means for detecting IL-1B –511 allele 2 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 2 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

10. Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of U.S. Patent No. 6,746,839. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '839 are drawn to methods and kits which require the use of the reagents for detecting IL-1B –

511 allele 1 and allele 2, particularly wherein the means is an allele specific oligonucleotide or a primer specific extension nucleic acid. Claims 1-5 and 14-49 of '877 do not specifically recite packaging the means for detecting IL-1B –511 allele 1 or 2 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 1 or 2 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

11. Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,268,142. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '142 are drawn to methods and kits which require the use of the reagents for detecting IL-1B –511 allele 1 and allele 2, particularly wherein the means is an allele specific oligonucleotide or a primer specific extension nucleic acid. The claims of '142 do not specifically recite packaging the means for detecting IL-1B –511 allele 1 or 2 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 1 or 2 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

12. Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,251,598. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '598 are drawn to methods which require the use of the reagents for detecting IL-1B –511 allele 2, particularly wherein the means is an allele specific restriction enzyme or a primer which amplifies and detects the IL-1B –511 allele 2 (which is considered to constitute a nucleic acid that detects IL-1B –511 allele 2 and a nucleic acid for primer specific extension). Regarding present claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the nucleic acids of '598 meet the limitations of the nucleic acids of present claim 17. The claims of '598 do not specifically recite packaging the means for detecting IL-1B –511 allele 2 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 2 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

13. Claims 1, 3, 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,706,478. Although the conflicting claims are not identical, they are not

patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '478 are drawn to methods which require the use of the reagents for detecting an IL-1B –511 allele 2, wherein the means is an allele specific oligonucleotide or a primer (which are considered to constitute a nucleic acid that hybridizes to an IL-1B –511 allele, and a nucleic acid for primer specific extension). The claims of '478 do not specifically recite packaging the means for detecting IL-1B –511 allele 2 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 2 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

14. Claims 1, 3, 5 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending U.S. Application No. 10/914,396. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 or allele 2 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '396 are drawn to methods which require the use of the reagents for detecting an IL-1B –511 allele 2, wherein said reagents include allele specific hybridization probes and primer specific extension nucleic acids (which are considered to constitute a nucleic acid that hybridizes to an IL-1B –511 allele, and a nucleic acid for primer specific

extension). Regarding present claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the nucleic acids of '396 meet the limitations of the nucleic acids of present claim 17. The claims of '396 do not specifically recite packaging the means for detecting IL-1B –511 allele 2 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 2 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1, 3, 5 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending U.S. Application No. 11/283,168. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. The claims of '168 are drawn to methods which require the use of the reagents for detecting an IL-1B –511 allele 1. When read in light of the specification, the means for detecting an IL-1B –511 allele 1 includes a nucleic acid that hybridizes to an IL-1B –511 allele, and a nucleic acid for primer specific extension. Regarding present claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to

a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the nucleic acids of '168 meet the limitations of the nucleic acids of present claim 17. The claims of '168 do not specifically recite packaging the means for detecting IL-1B –511 allele 1 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the means for detecting IL-1B –511 allele 1 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B -511 alleles.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1, 3, 5 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending U.S. Application No. 10/838,503. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a means for detecting allele 1 of the –511 marker of IL-1B, wherein the means may be a nucleic acid molecule that hybridizes to said allele. Regarding present claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the nucleic acids of '503 meet the limitations of the nucleic acids of present claim 17. The claims of '503 are also drawn to kits comprising a means for detecting an IL-1B –511 allele. In particular, in the claims of '503, the means for detecting an IL-1B –511 allele is a primer for

amplifying IL-1B –511 sequences (see SEQ ID NO: 13 and 14 therein), which is considered to constitute a nucleic acid which hybridizes to IL-1B –511 allele 1 and 2 and a nucleic acid for a primer specific extension.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, and 17 rejected under 35 U.S.C. 102(e) and 102(a) as being anticipated by Kornman (U.S. Patent No. 5,686,246; cited in the IDS).

Kornman (e.g., paragraphs 1, 14 and 18 and claim 9) discloses kits comprising a means for determining a genetic polymorphism pattern, wherein said means for determining a genetic polymorphism pattern are defined as including primers, amplification reagents and the restriction enzyme AvaI (see, e.g., paragraphs 5 and 31). In particular, Kornman teaches that the primers used for detecting the IL-1B –511 allele

1 and 2 include primers referred to therein as SEQ ID NO: 3 and 4 (paragraph 32). The primers of Kornman are considered to be a means for performing a primer specific extension reaction as required by present claim 3. Further the primers constitute an isolated nucleic acid which hybridizes to the IL-1B –511 allele 1 and 2. Regarding claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the primers of Kornman meet the limitations of the nucleic acids of present claim 17. Thereby, the kits of Kornman anticipate the claimed invention.

Additionally, Kornman teaches isolated nucleic acids that comprise IL-1B –511 allele 1 or allele 2 (see paragraph 28 and 31-40). It is noted that in the absence of any recitation in the claims or any direction in the specification to the contrary, the recitation in the claims of a "kit" reads on component parts capable of being assembled or a plurality of elements grouped together as a kit. Accordingly, the word "kit" does not impart any additional special structural or functional features which distinguishes the claimed kit over the isolated nucleic acids of Kornman. Since the nucleic acids of Kornman have the property of being a means for detecting an IL-1B –511 allele 1 or 2 (claims 1 and 3), a means for performing a hybridization reaction (claim 3), and are a nucleic acid which hybridizes to a nucleotide of allele 1 or 2 of IL-1B –511 (claims 5 and 17), the nucleic acids of Kornman anticipate the claimed invention.

18. Claims 1, 3, 5 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Francis et al (U.S. Patent No. 6,210,877).

Francis (e.g., paragraphs 26 and 29) discloses kits comprising a means for determining a genetic polymorphism pattern, wherein said means for determining a genetic polymorphism pattern are defined as including primers, amplification reagents and the restriction enzyme of AvaI (see, e.g., paragraphs 36 and 47). In particular, Francis teaches that the primers used for detecting the IL-1B –511 allele 1 and 2 include primers referred to therein as SEQ ID NO: 3 and 4 (paragraph 36). The primers of Francis are considered to be a means for performing a primer specific extension reaction as required by present claim 3. Further the primers constitute an isolated nucleic acid which hybridizes to the IL-1B –511 allele 1 and 2. Regarding claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the primers of Francis meet the limitations of the nucleic acids of present claim 17. Thereby, the kits of Francis anticipate the claimed invention.

Additionally, Francis teaches isolated nucleic acids that comprise IL-1B –511 allele 1 or allele 2 (see paragraph 28 and 31-40). It is noted that in the absence of any recitation in the claims or any direction in the specification to the contrary, the recitation in the claims of a "kit" reads on component parts capable of being assembled or a plurality of elements grouped together as a kit. Accordingly, the word "kit" does not impart any additional special structural or functional features which distinguishes the claimed kit over the isolated nucleic acids of Francis. Since the nucleic acids of Francis have the property of being a means for detecting an IL-1B –511 allele 1 or 2 (claims 1

and 3), a means for performing a hybridization reaction (claim 3), and are a nucleic acid which hybridizes to a nucleotide of allele 1 or 2 of IL-1B –511 (claims 5 and 17), the nucleic acids of Francis anticipate the claimed invention.

19. Claims 1, 3, 5, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Mansfield (Gastroenterology. 1994. 196: 637-642).

Mansfield teaches primers which hybridize to and amplify the IL-1B –511 allele 1 and 2 (see Table 2). Regarding claims 1 and 2, the primers of Mansfield are considered to be a means for detecting an IL-1B –511 allele. Regarding claim 3, the primers of Mansfield have the property of being useful performing a primer specific extension reaction. Regarding claim 5, the primers constitute an isolated nucleic acid which hybridizes to the IL-1B –511 allele 1 and 2. Regarding claim 17, the claim as broadly written encompasses kits comprising nucleic acids that hybridize with any specificity to a nucleic acid comprising a C or T or to any nucleic acid that hybridizes to any region of IL-1B. Accordingly, the primers of Mansfield meet the limitations of the nucleic acids of present claim 17. Further, Mansfield teaches methods of using said primers to amplify the IL-1B –511 allele 1 and 2. The resulting amplified nucleic acid is considered to be a nucleic acid that hybridizes to a nucleotide of the IL-1B –511 allele 1 or 2.

It is noted that in the absence of any recitation in the claims or any direction in the specification to the contrary, the recitation in the claims of a "kit" reads on component parts capable of being assembled or a plurality of elements grouped together as a kit. Accordingly, the word "kit" does not impart any additional special structural or functional features which distinguishes the claimed kit over the isolated

nucleic acids of Mansfield. Since the primers and amplified nucleic acids of Mansfield have the property of being a means for detecting an IL-1B –511 allele 1 or 2 (claims 1 and 3), a means for performing a hybridization reaction (claim 3), and are a nucleic acid which hybridizes to a nucleotide of allele 1 or 2 of IL-1B –511 (claims 5 and 17), the primers and amplified nucleic acids of Mansfield anticipate the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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